



EU systems for traceability and security features of tobacco products

– Stakeholder session –

*Directorate-General for Health and Food Safety,
European Commission*

**3rd Regional Workshop
Madrid, 15 March 2018**



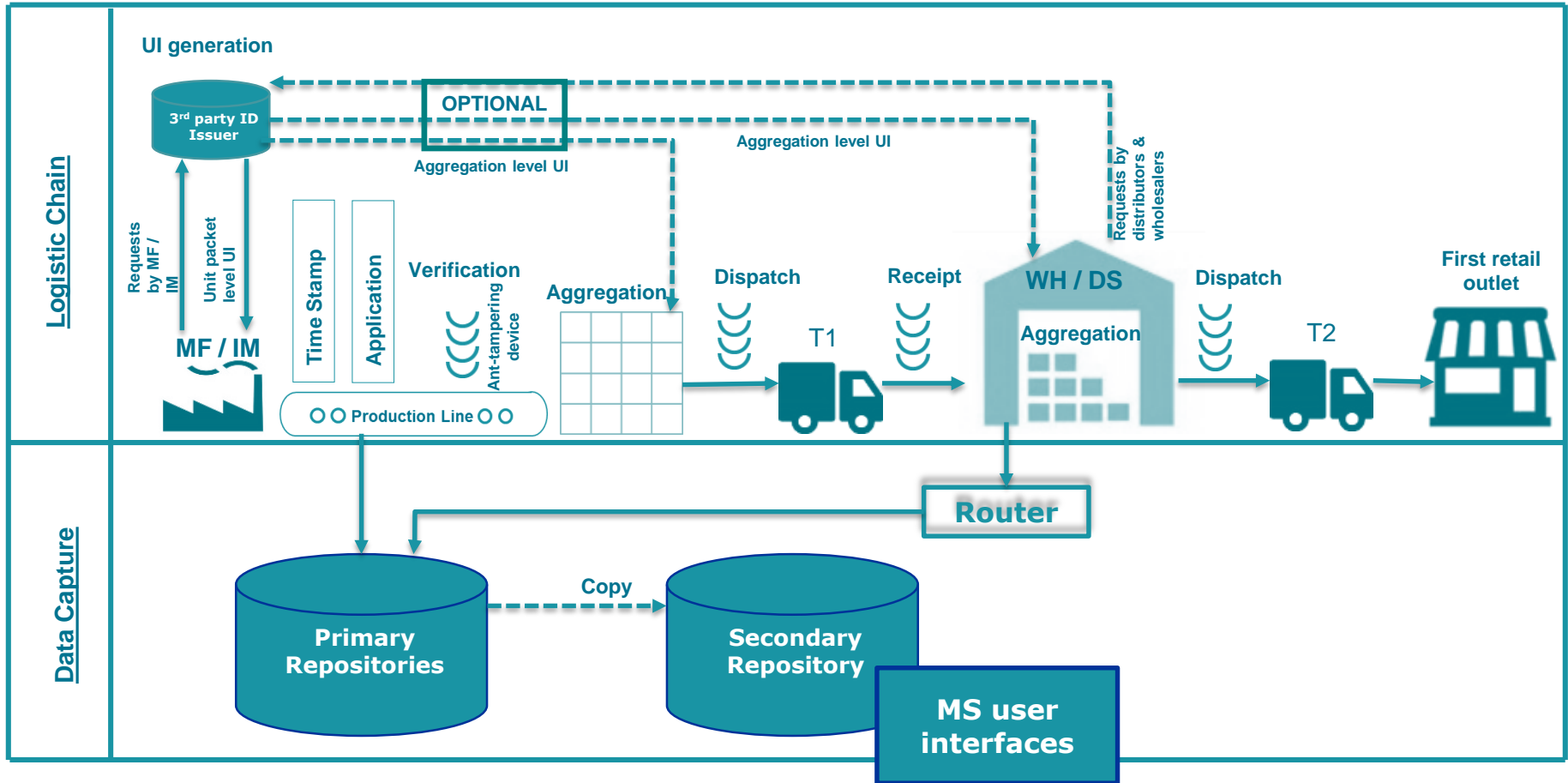
AGENDA

1. General introduction & timeframe
2. Session for manufacturers & importers
3. Session for wholesalers & distributors
4. Session for solution providers
5. Concluding remarks

TRACEABILITY SYSTEM

- INTRODUCTION -

Operational system structure



TRACEABILITY SYSTEM

- TIMEFRAME -

Timeframe – ID issuer

Reference point: COM Implementing Regulation

- Entry into force on 20th day following publication in OJ
- Date (estimate): **15 May 2018**

Appointment:

- No later than one year following entry into force → **15 May 2019**

Timeframe – Primary repository

Reference point: COM Delegated Regulation

- Entry into force on 20th day following publication in OJ
- Date (estimate): **15 May 2018**

Selection/contracting procedure (see Annex I, Part A):

Step	Task	Deadline
1	MF/IMP shall notify to COM the proposed provider, incl. draft contract, declarations, correspondence table	15/07/18
2	Approval/rejection of proposed provider by COM	15/08 – 15/10/18
3	MF/IMP shall propose alternative provider where initial proposal was rejected by COM	15/09 – 15/11/18

→ Different deadline for MF/IMP of products other than cigarettes/RYO

Timeframe – Secondary repository

Reference point: COM Delegated Regulation

- Entry into force on 20th day following publication in OJ
- Date (estimate): **15 May 2018**

Selection/contracting procedure (see Annex I, Part B):

Step	Task	Deadline
1	COM starts appointment procedure for provider of secondary repository	15/11/18
2	COM appoints provider of secondary repository	15/01/19
3	Contracts between providers of primary repository and provider of secondary repository must be concluded and submitted to COM	15/02/19

Timeframe – Secondary repository

Coordination tasks (Art. 28):

Step	Task	Deadline
1	List of specifications required for data exchange with secondary repository and router; communicate it to providers of primary repositories	15/03/19
2	Establish data dictionary; communicate it to providers of primary repositories	15/03/19

→ Start of system testing period: **20/03/2019**

TRACEABILITY SYSTEM: MANUFACTURERS & IMPORTERS

- MAIN RESPONSIBILITIES -

Identifier codes

1. Economic identifier code (Arts. 14 & 15).
 2. Facility identifier code (Arts. 16 & 17).
 3. Machine identifier code (Arts. 18 & 19).
- Required for all manufacturers and importers;
 - Request must be sent to the relevant ID issuer(s);
 - Transmits code within 2 working days following the request.
 - In duly justified cases, MS may request a code to be deactivated;
 - No fee for generation of identifier codes.

Unique identifier (unit level)

- Request UI from competent ID issuer; delivery method: electronically (default), physically (at discretion of MS);
 - 6 months validity of UIs (from date of receipt to application);
- Marking of unit packets with a unique identifier (Art. 6);
- Verification as to correct application/readability of UI (Art. 7);
 - Anti-tampering devices (declaration of independence);
 - Applicable **derogations**: '< 120mil UIs per year' (1y), 'SMEs' (2y), 'fully manual production processes' (∞).
- Prescribed structure of unit level UIs:

ID Issuer – independent 3rd party

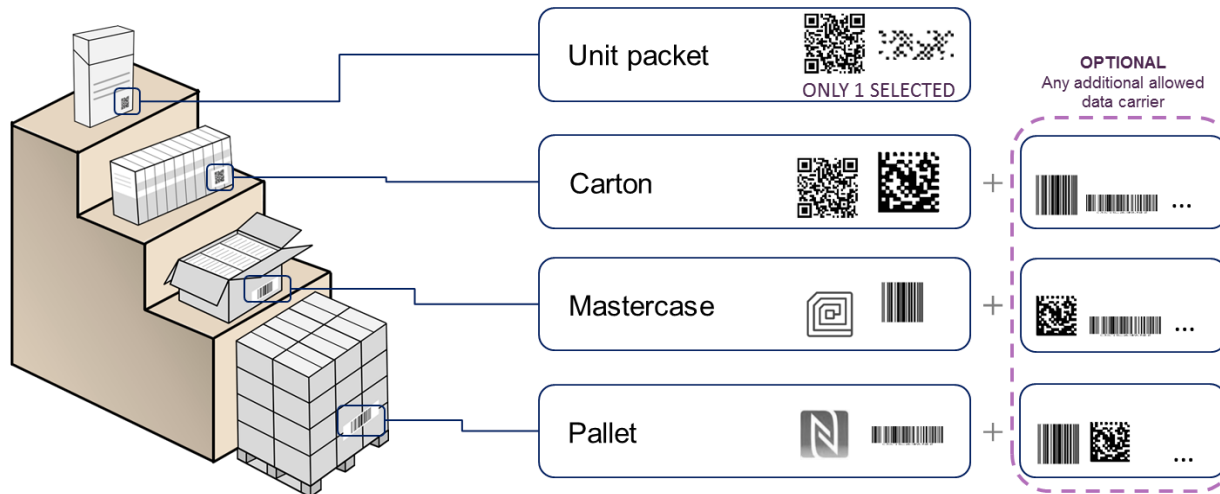
prefix	serial number	product code	YYMM DDhh
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Note: position of 'prefix' and 'time stamp' are fixed.

Unique identifier (aggregated level)

- Generation of unique identifiers for aggregated levels by ID issuers **or** by economic operators (Art. 10).
- Request to competent ID issuer:
 - Electronic delivery only;
 - Prescribed structure (similar to unit level UIs).
- Self-generation by economic operator:
 - Generation of code in accordance with ISO/IEC 15459-1:2014 or 15459-4:2014.
- Link between aggregated level and unit level UIs.

Permitted data carriers



- Electronic UI delivery → MF/IMP responsible for encoding;
- Physical UI delivery → ID issuer responsible for encoding;
- Time stamp may be added separately as human readable code;
- Marking "TTT" may be added next to data carrier.

Repository system

- One primary repository per manufacturer/importer (Art. 26);
- Obligation to notify proposed provider to the COM; approval of provider carried out by COM (see Annex I, Part A).
- Required documentation:
 - Draft contract + table of correspondence (see Delegated Regulation);
 - Written declaration of technical expertise (see Art. 25);
 - Written declaration of legal/financial independence.
- Bear costs for repositories system
(proportionate to the number of unit level UIs).

Recording/transmission of product movements

Recording of information on product movements (Art. 32)

- Required for: application of UI, dispatch, arrival, trans-loading;
- Disaggregation of aggregated level UI intended for reuse (i.e. those generated by economic operators).

Transmission of information on product movements (Art. 32)

- Transmission of information to primary repository;
- Stolen/ destroyed products require deactivation request;
- Correct transmission = positive acknowledgment from repository.

→ see section 3, Annex II

Recording/transmission of transactional information

- Required for: issuing of order number/invoice, payment receipt (Art. 33);
 - Once the respective event occurred / event can be linked to unit level UIs concerned.
- Responsibility to transmit information lies with the vendor.
- Transmission of information to primary repository;
- Correct transmission = positive acknowledgment from repository.

→ **See section 4, Annex II**

Time frame for transmission of information

Within **3 hours from the** occurrence of the event

- Required for the following events:
 - Application of unit level and aggregated level UIs;
 - Arrival of tobacco products at a facility;
 - Transactional events.
- Applicable only from 20 May 2028; until then **24h rule** applies.
- General **derogation** (i.e. 24h rule applies permanently) for
 - Undertakings/group of undertakings which handle <120mil UI per year;
 - Undertakings/group of undertakings that meet the definition of SME.

Within **24 hours prior to** the occurrence of the event

- Required for the following events:
 - Dispatch of tobacco products from a facility;
 - Trans-loading.

SECURITY FEATURES: MANUFACTURERS & IMPORTERS

- MAIN ACTIVITIES -

Security feature

- MS communicate to MF/IMP the permitted combination(s) of authentication elements that are to be used to form a security feature (Art. 3(3));
 - Communication deadline: **20/09/2018.**
- Independence criteria for at least one provider of an authentication element used in a security feature (Art. 3(2) conj. Art. 8);
- MS may introduce rotation schemes; compromised security features must be replaced and EO informed (5 days) (Art. 6).

Tax stamp as the security feature

- MS must ensure that tax stamps are used as '*the security feature*' only if they are compliant with all requirements (Art. 4(1));
- For non-compliant tax stamps, MS will communicate to MF/IMP additional information necessary for them to develop a compliant security feature based on the tax stamp (Art. 4(2));
 - Communication deadline: **20/09/2018** (Art. 4(3)).
- Note: MS may decide to make available the authorised security feature(s) to MF/IMP directly via a trusted third party .

TRACEABILITY AND SECURITY FEATURES: MANUFACTURERS & IMPORTERS

- FINANCIAL ASPECTS -

Cost implications by preferred policy options:

Preferred policy options	Annualised cost (EUR)	Cost per unit pack (EUR)
1a/3: Mixed solution (industry and third party)	8 digit figure	Less than €0.01
1b/1: Near real time reports	8 digit figure	
1c/3: Combined model	Low 8 digit figure	
2/4: Limited data carriers per level (and optional)	8 digit figure	
Total (Article 15 TPD)	Low 9 digit figure	
3/2: Printing or affixing or a combination of printing and affixing	8 digit figure	
Total (Articles 15 & 16 TPD)	Low 9 digit figure	

Distribution of costs and benefits per stakeholder group:

Affected stakeholders	Social benefits	Economic benefits	Economic costs
Competent authorities	9 digit figure	10 digit figure	7 digit figure
Economic operators, incl.:	n/a	8 digit figure	9 digit figure
- manufacturers/importers		8 digit figure	8 digit figure
- distributors/wholesalers		7 digit figure	8 digit figure
- retailers		7 digit figure	n/a
General public	10 digit figure	n/a	n/a
Total (EUR)	10 digit figure	10 digit figure	9 digit figure

→ very favourable benefit-cost ratio



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TRACEABILITY SYSTEM: DISTRIBUTORS & WHOLESALERS

- MAIN RESPONSIBILITIES -

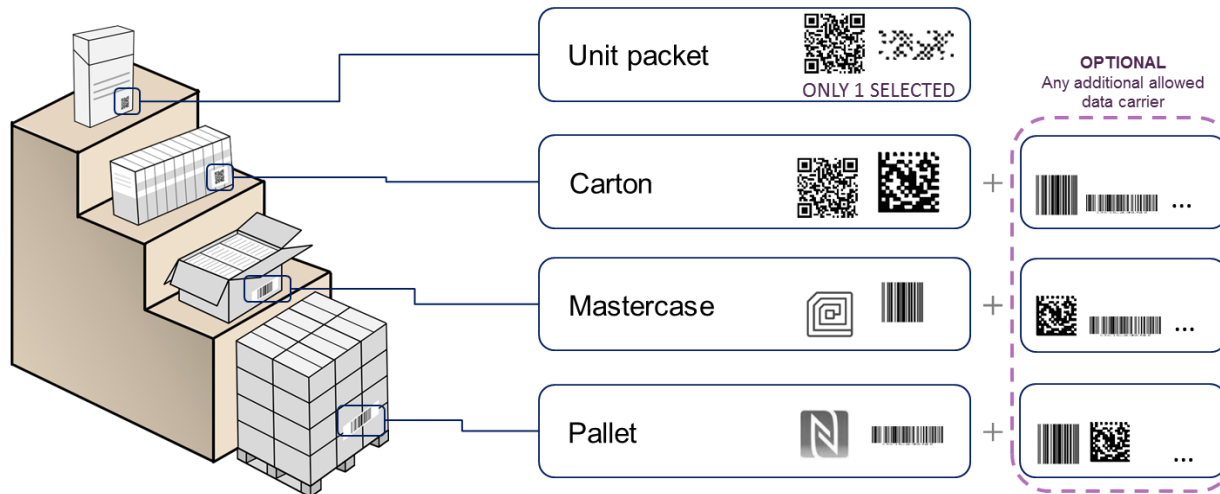
Identifier codes

1. Economic identifier code (Arts. 14 & 15).
2. Facility identifier code (Arts. 16 & 17).
 - Applies to all other economic operators (EO) involved in tobacco trade (distributors, wholesalers, transporting companies, including operators of first retail outlets);
 - Retail outlets: request for identifier code may also be discharged by another EO;
 - Request must be sent to relevant ID issuer(s);
 - Transmits code within 2 working days following the request.
 - In duly justified cases, MS may request an existing code to be deactivated;
 - No fees for generation of identifier codes.

Unique identifier (aggregated level)

- Marking of aggregated packaging: unique identifiers may be requested from the relevant ID issuer **or** generated directly by the economic operator (Art. 10).
- Request to relevant ID issuer:
 - Electronic delivery only;
 - Prescribed structure (same as for unit level UIs).
- Self-generation:
 - Generation of code in accordance with ISO/IEC 15459-1:2014 or 15459-4:2014.
- Link between aggregated level and unit level UIs.

Permitted data carriers



- Electronic UI delivery → EO responsible for encoding;
- (Physical UI delivery → ID issuer responsible for encoding);
- Time stamp may be added separately as human readable code;
- Marking "TTT" may be added next to data carrier.

Recording/transmission of product movements

Recording of information on product movements (Art. 32)

- Required for: application of UI, dispatch, arrival, trans-loading;
- Special cases: vending machines, vending vans;
- Disaggregation of aggregated level UI intended for reuse (i.e. those generated by economic operators).

Transmission of information on product movements (Art. 32)

- Transmission of information via router to secondary repository;
- Stolen/ destroyed products require deactivation request;
- Correct transmission = positive acknowledgment from repository.

→ see section 3, Annex II

Recording/transmission of transactional information

- Required for: issuing of order number/invoice, payment receipt (Art. 33);
 - Once the respective event occurred / event can be linked to unit level UIs concerned.
- Responsibility to transmit information lies with the vendor.
- Transmission of information via router to secondary repository;
- Correct transmission = positive acknowledgment from repository.

→ **See section 4, Annex II**

Time frame for transmission of information

Within **3 hours from the** occurrence of the event

- Required for the following events:
 - Application of unit level and aggregated level UIs;
 - Arrival of tobacco products at a facility;
 - Disaggregation (where UI is intended for reuse);
 - Delivery to multiple retail outlets via a vending van;
 - Transactional events.
- Applicable only from 20 May 2028; until then **24h rule** applies.
- General **derogation** (i.e. 24h rule applies permanently) for
 - Undertakings/group of undertakings which handle <120mil UI per year;
 - Undertakings/group of undertakings that meet the definition of SME.

Within **24 hours prior to** the occurrence of the event

- Required for the following events:
 - Dispatch of tobacco products from a facility;
 - Trans-loading.



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TRACEABILITY AND SECURITY FEATURES: SOLUTION PROVIDERS

- MAIN ACTIVITIES -

ID ISSUER

Selection and appointment by Member States (Art. 3)

- Compliance with ISO 15459-2:2015;
- Application to Registration Authority for registration and assignment of an Issuing Agency Code (IAC);
- Allocation of IAC from character A to Z, and 0 to 9 (GS1) depending on specific criteria;
- List of existing issuing agencies is available online.

Examples of registered Issuing Agencies

1. Register ordered by Issuing Agency Name		
ABOL SOFTWARE INC.	LN	ABOL SOFTWARE INC. 413 Creekstone Ridge Woodstock GA 30188 USA
Bosch und Siemens Hausgerate GmbH	VBS	Bosch und Siemens Hausgeräte GmbH Carls-Wery-Strasse 34 D- 81739 MUNCHEN GERMANY
Ghana Revenue Authority	GH	Ghana Revenue Authority PMB, TUC Post Office Accra GHANA
DALO Danish Defence Acquisition and Logistics Organization	KDK	DALO Postbox 220 Arsenalvej 55 9800 Hjørring DENMARK
DHL Express Benelux	VGL	DHL Express Benelux Terminalweg 36 3821 AJ AMERSFOORT THE NETHERLANDS

Source: http://www.aimglobal.org/?Reg_Authority15459

ID ISSUER

- Subcontracting only permitted if contractor's identity is known to Member State (para. 2);
- Independence requirement (para 3; see Art. 35);
 - Legal and financial independence, absence of conflict of interest.
- Ensure continuity and exit plan in the case an ID issuer is being replaced (para. 8);
- ID issuer may charge fees to the economic operators (for UI generation) (para. 9);
 - Non-discriminatory, proportionate.

Anti-tampering devices

"... device allowing for the recording of the verification process following the application of each unit level unique identifier by means of a video or a log file, which once recorded cannot be further altered by an economic operator."

- Device must be supplied and installed by an independent party
 - Declaration of independence (provider > MF/IMP > Member State/COM);
 - See Art. 35 for independence criteria.

Primary repository

- One repository per manufacturer/importer;
- Technical requirements → see Arts. 25, 26;
- Access (physical/virtual) only by MS, Commission, auditors;
- Must be physically located on EU territory;
- Contractual requirements → see Delegated Regulation
 - Technical expertise;
 - Legal and financial independence (see Art. 35).
- Approval of provider by the Commission → see Part A, Annex I.

Secondary repository

- Central storage, hosts global (up-to-date) copy of all primary repositories data;
- Technical requirements → see Arts. 25, 27, 28, 29;
- Contains routing service (= reporting entry point for WS/DB);
- Establishes data dictionary /data exchange formalities to be used by providers of primary repositories and ID issuers;
- Graphical/non-graphical user interfaces (database search function for MS/COM/auditor);
- Appointment carried out by COM amongst providers of primary repositories (Part B, Annex I).

Security features

- Security feature composed of (at least) 5 authentication elements:
 - 1 overt (ISO 12931:2012, category 'overt');
 - 1 semi-covert (ISO 12931:2012, category 'covert', off-the-shelf tools);
 - 1 covert (ISO 12931:2012, category 'covert', purpose built tools).
- Independence criteria for at least one provider of an authentication element used in a security feature(Art. 3(2) conj. Art. 8);
- MS define permitted composition(s) of security features;
 - Tax stamp may be used to define the permitted security feature.



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– END –

THANK YOU FOR YOUR ATTENTION